



THE MARY ANN KNIGHT INTERNATIONAL INSTITUTE OF PEDIATRICS  
FOUNDED AS VARIETY CHILDREN'S HOSPITAL

Pediatric Ophthalmology Consultants  
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The Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 106 1  
Rockville, Maryland 20852

To Whom It May Concern:

I am ophthalmic surgeon. I use donor cornea and donor scleral tissue in my practice. A recent ruling has been made as part of Food and Drug regulations, 21CFR Parts 210, 216, 820 and 1271 (Docket No. 97N-4845). That ruling states that the next-of-kin must be notified for a series of questions before tissue can be considered suitable for donation. Corneal transplant tissue is precious. Time in obtaining that tissue for surgical use is short. The Florida Lions Eye Bank has pointed out that the additional time and-expense involved in obtaining a telephonic or face to face interview with next-of-kin, even in medical examiner cases, will compromise quality medical care. It is unlikely that it will add any to the quality of medical care since the questions asked are not likely to provide the critical sensitive answers of communicable diseases in donor tissue. The main infective agents of concern are viral and it is unlikely that the family member, even a next of kin, will disclose or even knows the nature of infection if it is not readily apparent prior to the time of death. Although it sounds like it should be effective, our clinical experience is that such an additional step will not safeguard from infection but only reduce the effectiveness of the eye banks in the community to provide surgical quality tissue.

As an ophthalmic surgeon, I would urge you to reconsider these above rulings. Sometimes theory and practicality conflict. I would hope that experience, common sense and clinical judgement can be used to best support quality medical care. In this particular case, additional questions to next-of-kin may not provide additional information and in fact, is unlikely to provide additional information. Making rules because they might help is not in the best interest of our patients or our medical care in this country.

Sincerely,

Cleve W. Howard, M.D.

CWH/ra

CC: Senators Bob Graham, Connie Mack  
Representatives Charles T. Canady, Dan Miller, Porter J. Goss, Dave Weldon, Mark Foley,  
Carrie Meek, Ileana Ros-Lehtinen, Robert Wexler, Peter Deutsch, Lincoln Diaz-Balart,  
E. Clay Shaw, Jr., Alcee Hastings

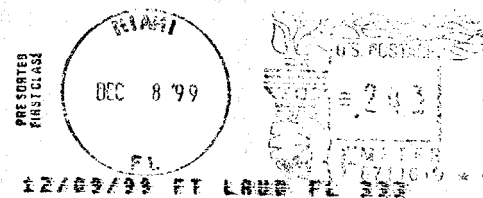
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